

**Notice of Allowability**

Application No.

10/053,102

Examiner

Steven D. Maki

Applicant(s)

FOX ET AL.

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1733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6-4-04.
2. ☒ The allowed claim(s) is/are 19,20 and 22-39.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☒ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☒ to Paper No./Mail Date 4.
    - (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date 061704.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 052604 and 060404.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Examiner's Amendment

1) An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Amend claim 19 as follows:

19. (currently amended) A method for producing a plurality of medical test implements, comprising the steps of:

~~folding first and second portions of a handle forming material toward one another;~~  
~~separating the first and second portions of the handle forming material;~~  
~~positioning a plurality of test elements, each having a predetermined length,~~  
~~between the first and portions of the handle forming material such that each test~~  
~~element is spaced apart from one another by a predetermined distance;~~  
~~mechanically mating the first and second portions of the handle forming material~~  
~~to one another with the plurality of test elements disposed therebetween; and~~  
folding a continuous sheet of handle forming material at a folding station such  
that first and second continuous portions converge toward each other;  
guiding the first and second continuous portions, respectively, over and under a  
separator device;

inserting a continuous deformable material between the first and second continuous portions of the folded sheet of handle forming material;

joining the first and second continuous portions together with the deformable material therebetween and then cutting deformable material to form a test element;

repeating the inserting and joining steps such that a plurality of spaced apart test elements are between the joined first and second portions of the folded sheet; and

perforating, scoring or cutting the joined first and second portions of the folded sheet of handle-forming material to form a plurality of medical test implements, each having a handle and a test element that is adapted to deform when a predetermined load is applied thereto.

In claim 20:

line 1 change "handle-forming material" to --sheet--

line 2 change "first and second portions" to --sheet--

Cancel claim 21.

In claim 22:

line 1 change "claim 21" to --claim 19--

line 1 change "elongate test element" to --continuous deformable material--

line 2 change "elongate test element" to --continuous deformable material--

In claim 23:

lines 2-3 change "elongate test element during the elongate test element" to --continuous deformable material--.

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In claim 26:

line 1 delete --predetermined--

In claim 30:

line 1 change "handle-forming member" to --sheet--

In claim 32:

change "plurality of testing implements" to --test elements--

In claim 36:

line 2 change "handle-forming member" to --sheet--

lines 2-3 change "mechanically mating" to --joining--

In claim 37:

line 2 change "mechanically mating" to --joining--

In claim 39:

change "handle-forming member" to --sheet--.

Cancel claims 40, 41 and 42.

In the specification:

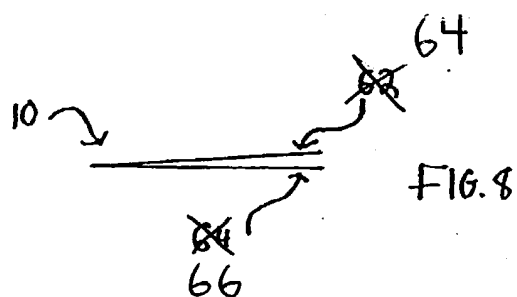
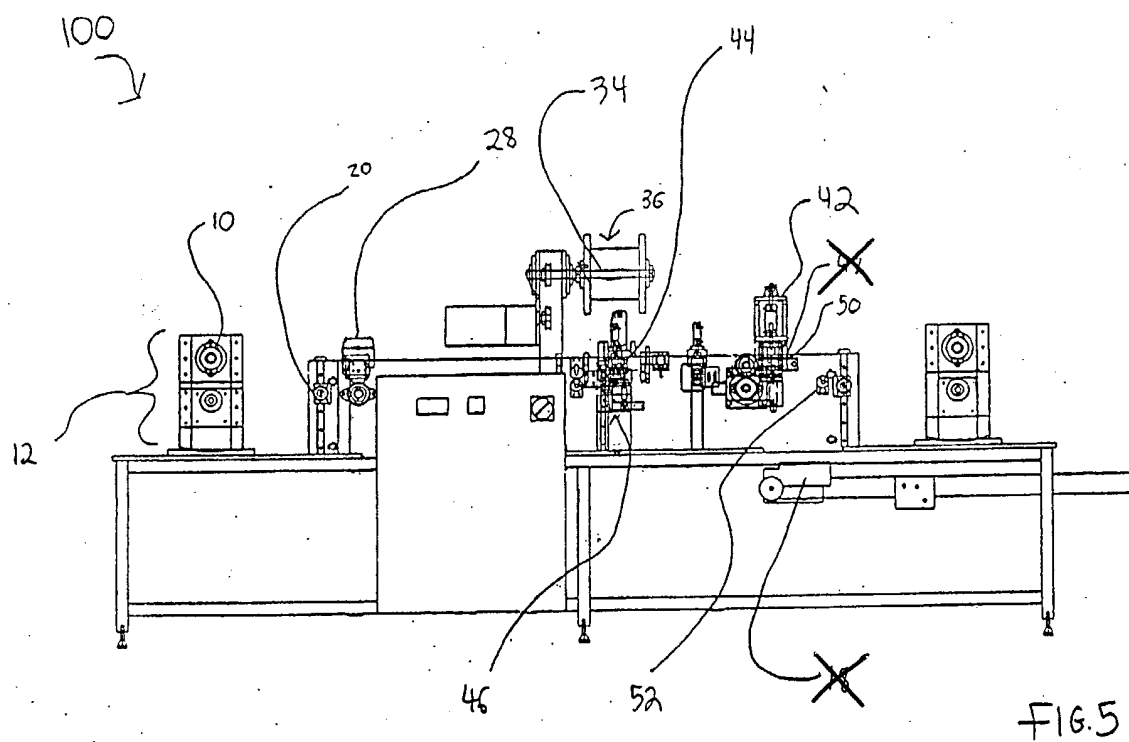
on line 4 of the replacement paragraph filed 12-22-03, change "62, 66" to

--64, 66--

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In the drawings:

Amend figures 5 and 8 as follows: In figure 5, delete reference numerals 18 and 48. In figure 8 change "62" to -66-



- 2) Authorization for this examiner's amendment was given in a telephone interview with Lisa Michaud on 6-4-04.

Reasons for Allowance

- 3) The following is an examiner's statement of reasons for allowance:

With respect to the step of "folding a continuous sheet of handle forming material at a folding station such that first and second continuous portions converge toward each other", support is found in the original disclosure for example at page 8 lines 11-14 and figure 6.

With respect to the step of "guiding the first and second continuous portions, respectively, over and under a separator device", support is found in the original disclosure for example at page 9 lines 12-20 and figure 6.

With respect to the steps of "inserting a continuous deformable material between the first and second continuous portions of the folded sheet of handle forming material" and "joining the first and second continuous portions together with the deformable material therebetween and then cutting deformable material to form a test element", support is found in the original disclosure for example in figure 4, figure 5, page 6 line 19 to page 7 line 3, page 9 line 21 to page 9 line 17.

The prior art of record whether taken singly or in combination fails to disclose, teach or suggest a method for producing a **plurality of medical test implements**, comprising the steps of guiding the first and second continuous portions, respectively, over and under a separator device; inserting a continuous deformable material between the first and second continuous portions of the folded sheet of handle forming material;

joining the first and second continuous portions together with the deformable material therebetween and then cutting deformable material to form a test element; in combination with the remaining claimed steps of folding a continuous sheet of handle forming material at a folding station such that first and second continuous portions converge toward each other; repeating the inserting and joining steps such that a plurality of spaced apart test elements are between the joined first and second portions of the folded sheet; and perforating, scoring or cutting the joined first and second portions of the folded sheet of handle-forming material to form a **plurality of medical test implements, each having a handle and a test element that is adapted to deform when a predetermined load is applied thereto.**

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

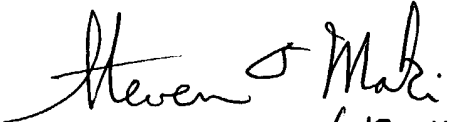
4) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven D. Maki whose telephone number is (571) 272-1221. The examiner can normally be reached on Mon. - Fri. 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (571) 272-1226. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Steven D. Maki  
June 17, 2004

  
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6-17-04